PolyPid Announces 750th Patient Enrolled in SHIELD I Phase 3 Clinical Trial of D-PLEX in Abdominal Surgery

Unblinded Interim Analysis Expected in the Second Quarter of 2022

PETACH TIKVA, Israel, March 02, 2022 — PolyPid Ltd. (Nasdaq: PYPD) ("PolyPid" or the "Company"), a Phase 3 biopharmaceutical company focused on developing targeted, locally administered, and prolonged-release therapeutics using its proprietary PLEX technology, announced today that the 750th patient has been enrolled into its ongoing pivotal Phase 3 SHIELD I study evaluating D-PLEX$_{100}$ for the prevention of surgical site infections (SSIs) in abdominal surgery. Upon completion of the 30-day follow-up assessment for the 750th patient, based on an agreement with the U.S. Food and Drug Administration (FDA), an unblinded interim analysis will be conducted. This interim analysis is expected to occur during the second quarter of this year, and will allow for early trial conclusion due to efficacy, futility, or for sample size re-assessment.

"We are very pleased with the recent high rate of enrollment in SHIELD I, especially considering the recent disruption to hospitals caused by the surge of COVID-19 infections driven by the Omicron variant," stated Amir Weisberg, Chief Executive Officer of PolyPid. "The planned, unblinded interim analysis will strengthen the adaptive design of the study so that we can more precisely define the targeted patient enrollment range. It can also potentially allow for stopping the trial earlier than planned, if the efficacy results on SSIs are overwhelming."

The FDA has previously agreed, provided the Phase 3 study results are adequate, that a single pivotal study is sufficient for potential approval of D-PLEX$_{100}$ for the prevention of SSIs in colorectal (abdominal) surgery.

About D-PLEX$_{100}$

PolyPid's lead product candidate, D-PLEX$_{100}$, is a novel drug product candidate designed to provide local prolonged and controlled anti-bacterial activity directly at the surgical site to prevent SSIs. Following the administration of D-PLEX$_{100}$ into the surgical site, the PLEX technology enables a prolonged and continuous release of the broad-spectrum antibiotic doxycycline, resulting in high local concentration of the drug for a period of four weeks for the prevention of SSIs, with additional potential to prevent SSIs caused by antibiotic-resistant bacteria at the surgical site. D-PLEX$_{100}$ has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) for the prevention of SSIs in patients undergoing elective colorectal surgery. D-PLEX$_{100}$ has also received two Qualified Infectious Disease Product (QIDP) designations as well as two Fast Track designations for the prevention of post-abdominal surgery incisional infection and for the prevention of sternal wound infection post-cardiac surgery.

About PolyPid

PolyPid Ltd. (Nasdaq: PYPD), is a phase 3 biopharma company aiming to improve surgical outcomes through locally administered, controlled, extended-release therapeutics. PolyPid's proprietary PLEX (Polymer-Lipid Encapsulation matriX) technology pairs with medications, enables precise delivery of drugs at effective release rates, over pre-determined durations ranging from several days to months. PolyPid's lead product candidate D-PLEX$_{100}$ is in Phase 3 clinical trials for the prevention of abdominal and sternal surgical site infections (SSIs).
For additional company information, please visit polypid.com and follow us on Twitter and LinkedIn.

Forward-looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act and other securities laws. Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates" and similar expressions or variations of such words are intended to identify forward-looking statements. For example, the Company is using forward-looking statements when it discusses its expectations regarding the unblinded interim analysis and its timing and that interim analysis will potentially allow for an early trial stopping. Forward-looking statements are not historical facts, and are based upon management's current expectations, beliefs and projections, many of which, by their nature, are inherently uncertain. Such expectations, beliefs and projections are expressed in good faith. However, there can be no assurance that management's expectations, beliefs and projections will be achieved, and actual results may differ materially from what is expressed in or indicated by the forward-looking statements. Forward-looking statements are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in the forward-looking statements. For a more detailed description of the risks and uncertainties affecting the Company, reference is made to the Company's reports filed from time to time with the Securities and Exchange Commission ("SEC"), including, but not limited to, the risks detailed in the Company's Annual Report on Form 20-F filed on February 28, 2022. Forward-looking statements speak only as of the date the statements are made. The Company assumes no obligation to update forward-looking statements to reflect actual results, subsequent events or circumstances, changes in assumptions or changes in other factors affecting forward-looking information except to the extent required by applicable securities laws. If the Company does update one or more forward-looking statements, no inference should be drawn that the Company will make additional updates with respect thereto or with respect to other forward-looking statements.

References and links to websites have been provided as a convenience, and the information contained on such websites is not incorporated by reference into this press release. PolyPid is not responsible for the contents of third-party websites.

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